



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Banerjee *et al.*  
Patent No.: 6,667,344 B2  
Serial No.: 09/887,281  
Filed: June 22, 2001  
Issue Date: December 23, 2003

For: **BRONCHODILATING  
COMPOSITIONS AND METHODS**

Art Unit: 6268  
Examiner: Weddington, K.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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EV 417729032 US

Date of Deposit: January 14, 2004

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 C.F.R. §1.10 on the date indicated above and addressed to:

Commissioner for Patents  
U.S. Patent and Trademark Office  
P. O. Box 1450  
Alexandria, VA 22313-1450

01/14/04

Date

Jonathan Ong

22 JAN 2004

REQUEST FOR CERTIFICATE OF CORRECTION  
PURSUANT TO 37 C.F.R. §§ 1.322 and 1.323

Attn: Certificate of Correction Branch  
Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.322, the patentee respectfully requests that a Certificate of Correction be issued for the above-referenced patent to correct the following error:

IN THE REFERENCES CITED [56]:

Please add the following to the OTHER PUBLICATIONS:

Lipworth *et al.*, "Effects of treatment with formoterol on bronchoprotection against methacholine," *Am. J. Med.* 104:431-438 (1998).

**U.S. Patent No. 6,667,344 B2**  
**Banerjee *et al.***  
**REQUEST FOR CERTIFICATE OF CORRECTION**

**REMARKS**

Duplicates of a Certificate of Correction (Form PTO-1050) incorporating the above change is included with this Request. Because the error was introduced by the PTO no fee is due. If it is determined that a fee is due the Office is hereby authorized to charge the fee to Deposit Account No. 50-1213.

This Certificate of Correction seeks to correct an error introduced by the PTO in the References Cited [56]. An Information Disclosure Statement citing the reference listed above was mailed on November 22, 2002. The Form PTO-1449, specifically page 6, citing the reference (item DA) was considered, initialed and returned by the Examiner in an Office Action mailed January 22, 2003. Copies of the Information Disclosure Statement filed on November 22, 2002, date-stamped postcard, and the Office Action and initialed Form PTO-1449 mailed on January 22, 2003 are provided herewith as evidence. The cited document was not listed on the issued patent. This Certificate of Correction seeks to correct the References Cited. These changes do not constitute new matter.

**U.S. Patent No. 6,667,344 B2**  
**Banerjee *et al.***  
**REQUEST FOR CERTIFICATE OF CORRECTION**

Patentee respectfully requests correction of these errors by issuance of a Certificate of Correction.

\* \* \*

Respectfully submitted,

HELLER EHRMAN WHITE & MCAULIFFE LLP

By: \_\_\_\_\_



Dale L. Rieger

Registration No. 43,045

Attorney Docket No.: 18025-1013  
**Address all correspondence to:**  
HELLER EHRMAN WHITE & MCAULIFFE LLP  
Stephanie L. Seidman  
4350 La Jolla Village Drive, 6th Floor  
San Diego, CA 92122-1246  
Telephone: (858) 450-8400  
E-MAIL: seidman@hewm.com



UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

*TMK*

22 JAN 2004

PATENT NO.: 6,667,344 B2

DATED: December 23, 2003

INVENTOR(S): Banerjee *et al.*

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

*Title Pg. Item 56,*  
~~IN THE REFERENCES CITED, 1561~~

Please add the following ~~to the~~ OTHER PUBLICATIONS:

Lipworth *et al.*, "Effects of treatment with formoterol on bronchoprotection against methacholine," *Am. J. Med.* 104:431-438 (1998). *C*

Mailing Address of Sender:  
Stephanie L. Seidman, Esq.  
HELLER, EHRMAN, WHITE & McAULIFFE  
4350 La Jolla Village Drive, 7th Floor  
San Diego, California 92122-1246



UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO.: 6,667,344 B2

DATED: December 23, 2003

INVENTOR(S): Banerjee *et al.*

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

**IN THE REFERENCES CITED [56]:**

Please add the following to the OTHER PUBLICATIONS:

Lipworth *et al.*, "Effects of treatment with formoterol on bronchoprotection against methacholine," *Am. J. Med.* **104**:431-438 (1998).

22 JAN 2004

Mailing Address of Sender:  
Stephanie L. Seidman, Esq.  
HELLER, EHRMAN, WHITE & McAULIFFE  
4350 La Jolla Village Drive, 7th Floor  
San Diego, California 92122-1246

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,667,344 B2  
DATED : December 23, 2003  
INVENTOR(S) : Banerjee et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

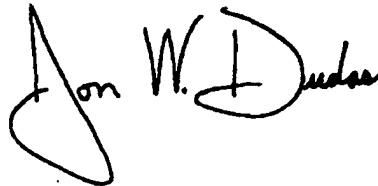
Title page,

Item [56], **References Cited**, OTHER PUBLICATIONS, please add the following:

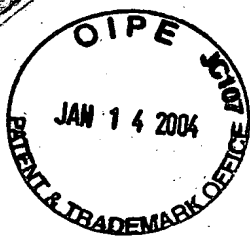
-- Lipworth *et al.*, "Effects of treatment with formoterol on bronchoprotection against methacholine," *Am. J. Med.* **104**:431-438 (1998). --

Signed and Sealed this

Twentieth Day of April, 2004

A handwritten signature in black ink, appearing to read "Jon W. Dudas". The signature is stylized with a large, looping initial "J" and a distinct "D".

JON W. DUDAS  
*Acting Director of the United States Patent and Trademark Office*



Main: (858) 450-8400  
Fax: (858) 587-5360

November 21, 2002

VIA FEDERAL EXPRESS

MOORELAND & MOORE  
2001 Jefferson Davis Highway  
Suite 407  
Arlington, VA 22202

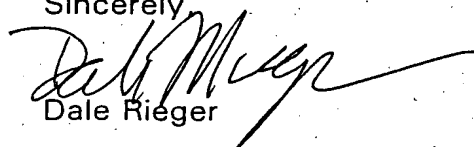
Re: Banerjee *et al.* U.S.S.N. 09/887,281 filed June 22, 2001  
*BRONCHODILATING COMPOSITIONS AND METHODS*  
Our Docket No. 18025-1013

Gentlemen:

Please deliver the enclosed documents for Art Unit 1617 to the U.S. Patent and Trademark Office on Friday, November 22, 2002. The documents enclosed are a Transmittal Letter (in duplicate), Supplemental Information Disclosure Statement, Forms PTO-1449 (7 pages) and cited references. In addition, please have the enclosed postcard date-stamped by the PTO and returned to us at your earliest convenience. We would also appreciate receiving a confirmation from you indicating that delivery of the enclosed documents has been made.

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to contact our office.

Sincerely,



Dale Rieger

DLR:MB



22 JAN 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Banerjee *et al.*  
Serial No.: 09/887,281  
Conf. No.: 6268  
Filed: June 22, 2001  
For: *BRONCHODILATING COMPOSITIONS AND METHODS*  
Art Unit: 1614  
Examiner: Weddington, K. E.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

Dear Sir:

Since this Supplemental Information Disclosure Statement is filed after receipt of a first Office Action on the merits for the above-captioned application, the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§ 1.97-1.98. Forms PTO-1449 (7 pages) and the cited references are provided herewith.

The documents listed on the Forms PTO-1449 and supplied herewith are in the English language, with the exception of Items T, U, W, AG, BB, BC, BL, BM and BX, which are in German language and Item CW, which is in the Japanese language. English-language Derwent abstracts for Items T, U, W, AG, BB, BC, BL,

22 JAN 2004



U.S.S.N. 09/887,281

Banerjee *et al.*

**Supplemental Information Disclosure Statement**

BM and BX are provided (Items CJ, CK, CL, CM, CN, CO, CP, CQ and CR, respectively). English-language abstract is provided on the first page of Item CW. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

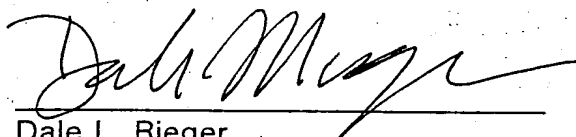
Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that the references, alone or in combination, are effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

\* \* \*

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

By:

  
Dale L. Rieger  
Registration No. 43,045

November 21, 2002

Attorney Docket No. 18025-1013

**Address all correspondence to:**

Stephanie Seidman, Esq.

HELLER EHRMAN WHITE & McAULIFFE LLP

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## Office Action Summary

JAN 14 2004

Application No.  
09/887,281

Applicant(s)

Banerjee et al.

Examiner  
Kevin E. WeddingtonArt Unit  
1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 22, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-61, 65-67, 71-73, 77-89, and 93-99 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 4-61, 65-67, 71-73, 77-89, and 93-99 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 and 1 6) ☐ Other:



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,281	06/22/2001	Partha S. Banerjee	18025-1013	6268

7590

01/22/2003

STEPHANIE L. SEIDMAN, ESQ.  
HELLER, EHRMAN, WHITE & MCAULIFFE LLP  
4350 LA JOLLA VILLAGE DRIVE  
6TH FLOOR  
SAN DIEGO, CA 92122

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/22/2003



Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

JAN 27 2003

HellerEhrman

Art Unit: 1614

Claims 1-61, 65-67, 71-73, 77-89 and 93-99 are presented for examination.

Applicants' amendment and information disclosure statement filed August 22, 2002 and November 22, 2002 have been received and entered.

The petition filed July 22, 2002 was granted on October 8, 2002, therefore, claims 1-61, 65-67, 71-73, 77-89 and 93-99 will be examined.

Accordingly, the rejections made under 35 U.S.C. 102(e) and 35 U.S.C. 103 as set forth in the previous Office action at pages 3-5 are hereby withdrawn so that new rejections can be made.

#### ***Claim Objections***

Claims 2 and 3 are objected to because the claims' limitations are not taught by the cited reference.

#### ***Claim Rejections - 35 U.S.C. § 112***

Claims 71-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification does not contain any test results or any experimental data showing the instant composition will, in fact, prevent or ameliorate one or more

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symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction especially in a mammal not presently at risk of or predisposed to developing such diseases or disorders.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 4-12, 18-21, 27-29, 35-38, 44-49, 54, 57-61, 77-79, 88, 89 and 94-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Hochrainer et al. (B) .

Hochrainer et al. teach a formoterol active substance concentrate in the form of a solution or suspension. The solution or suspension containing formoterol can be stored therein a period from several months possibly up to several years (column 1, lines 55-66). The reference also teaches the solution or suspension can be used in inhalers for inhalation or nasal therapy (see the abstract). Note particularly column 1, lines 47-52 states the formoterol solution or suspension can be formulated into aerosol formulation which is converted by means of a nebulizer. Clearly, the cited reference teaches the applicants' instant pharmaceutical composition of claim 1 and the addition of a nebulizer. The reference also

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teaches in column 2, lines 13-16, the polar fluids are preferred, particularly protic fluids (the same as applicants' polar solvents and protic solvents). Note particularly column 2, lines 57-64 for inorganic and organic salts that are used in the saline solutions (same as applicants' tonicity adjusting agents). Note particularly column 3, lines 42-45 teaches the pH of the formoterol of between 2.0 and 7.0, in which, the applicants' pH of about 2.0 to about 8.0 falls within the cited reference's pH range. Note particularly column 4, lines 55-68 and column 5, lines 1-6 teaches the buffer substances used in the solution (same as applicants' buffers). The reference also teaches the addition of other inhalatively active pharmaceutical substance such as anticholinergic and leukotriene antagonists (see column 8, claim 19), the same as applicants' additional ingredients of claims 77 and 94-99. Clearly, the cited reference anticipates the applicants' instant pharmaceutical composition, therefore, the instant pharmaceutical composition is unpatentable.

Claims 1, 4-12, 18-21, 27-29, 35-38, 44-49, 54, 57-61, 77-79, 88, 89 and 94-99 are not allowed.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1614

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-17, 22-26, 30-34, 39-43, 50-53, 55, 56, 58, 65-67, 71-73, 80-87, 92-93 and 97-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (B).

Hochrainer et al. was discussed above supra for its pharmaceutical composition comprising formoterol.

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred concentrate for the buffer. However, to determine a concentration having optimum effectiveness is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum concentrations to get the maximum effect of the buffer.

The instant invention differs from the cited reference in that the cited reference does not teach the concentration range of formoterol. However, to determine a concentration having optimum effectiveness is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum concentrations to get the maximum effect of formoterol.

The instant invention differs from the cited reference in that the cited reference does not teach concentration range of the anticholinergic agent. However, to determine a

Art Unit: 1614

concentration having optimum effectiveness is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum concentration to get the maximum effect of the anticholinergic agent.

Claims 13-17, 22-26, 30-34, 39-43, 50-53, 55, 56, 58, 65-67, 71-73, 80-87, 92, 93 and 97-99 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

### *Conclusion*

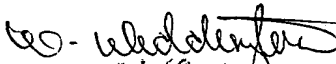
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner K. Weddington whose telephone number is (703) 308-1235.

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington

January 21, 2003

JAN 14 2004

FORM PTO-892

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

SERIAL NO.

09/887,281

GROUP ART  
UNIT

1614

ATTACHMENT  
TO PAPER NO.

16

## NOTICE OF REFERENCES CITED

APPLICANT(S)

Banerjee et al.

## U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	A	5,972,919	10-1999	Carling et al.	514	171	
	B	6,150,418	11-2000	Hochrainer et al.	514	630	10-1999
	C	6,161,536	12-2000	Redmon et al.	128	200.14	
	D	6,461,591	10-2002	Keller et al.	424	45	
	E						
	F						
	G						
	H						
	I						
	J						
	K						

## FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS
	L						
	M						
	N						
	O						
	P						
	Q						

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	R	
	S	
	T	
	U	

EXAMINER

Kevin E. Weddington

DATE

January 21, 2003

Form 892ccs2106b

\* A copy of this reference is not being furnished with this office action.  
(See Manual of Patent Examining Procedure, section 707.05(a).)

JAN 14 2004

Sheet 1 of 7

**UIPE**  
FORM PT 1449 (Modified)  
JAN 14 2004  
LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

ATTY. DOCKET NO.  
18025-1013

SERIAL NO.  
09/887,281

APPLICANT  
Banerjee *et al.*

FILING DATE  
June 22, 2001

GROUP  
1614

**RECEIVED**  
DEC 02 2002  
TECH CENTER 1600/2900

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
164	A	0	0	2	4	6	4	1	09/27/01	Yang	424	46	04/02/01
	B	0	0	3	2	1	4	9	03/14/02	Kensey	514	1	04/24/01
	C	0	0	6	1	8	3	5	05/23/02	Kensey	514	1	04/09/01
	D	0	0	8	1	2	6	6	06/27/02	Woolfe <i>et al.</i>	424	46	08/14/01
	E	0	0	9	9	0	1	3	07/25/02	Piccariello <i>et al.</i>	514	12	08/22/01
	F	0	1	0	3	2	6	0	08/01/02	Clarke <i>et al.</i>	514	630	08/15/01
	G	0	1	5	1	5	9	7	10/17/02	Banerjee <i>et al.</i>	514	629	07/22/01
	H	4	3	3	5	1	2	1	06/15/82	Phillipps <i>et al.</i>	424	241	02/13/81
	I	4	9	9	2	4	7	4	02/12/91	Skidmore <i>et al.</i>	514	653	08/23/89
	J	5	1	2	6	3	7	5	06/30/92	Skidmore <i>et al.</i>	514	651	11/29/90
	K	5	2	2	5	4	4	5	07/06/93	Skidmore <i>et al.</i>	514	651	02/19/92
	L	5	2	7	0	3	0	5	12/14/93	Palmer	514	171	09/03/91
	M	5	2	9	0	8	1	5	03/01/94	Johnson <i>et al.</i>	514	651	11/25/91
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	O	5	9	8	0	9	4	9	11/09/99	Trofast	424	489	01/09/98
	P	5	9	8	3	9	5	6	11/16/99	Trofast	141	1	01/09/98
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164	S	6	3	6	9	1	1	5	04/09/02	Ward	514	728	03/20/00

### FOREIGN PATENT DOCUMENTS

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EXAMINER

W. Widdows

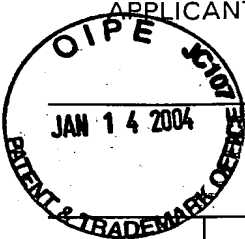
DATE CONSIDERED

1-17-03

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Title: **BRONCHODILATING COMPOSITIONS AND METHODS**

FORM PTO-1449 (Modified)

ATTY. DOCKET NO.  
18025-1013SERIAL NO.  
09/887,281LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENTAPPLICANT  
Banerjee *et al.*FILING DATE  
June 22, 2001GROUP  
1614

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS	Translation	
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W. Wheeler

DATE CONSIDERED

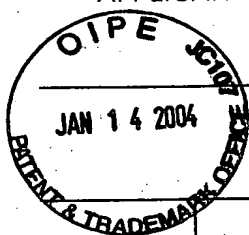
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													Yes	No
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X\* = English Language Derwent Abstract is provided.

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

kw	CG	Barnes, P.J., "Scientific rationale for inhaled combination therapy with long-acting $\beta_2$ -agonists and corticosteroids," <i>Eur. Respir. J.</i> <u>19</u> : 182-191 (2002)
	CH	Campestrini <i>et al.</i> , "Automated and sensitive method for the determination of formoterol in human plasma by high-performance liquid chromatography and electrochemical detection," <i>Journal of Chromatography B</i> <u>704</u> : 221-229 (1997)
	CI	Cazzola <i>et al.</i> , "Long-Acting $\beta_2$ -Agonists in the Treatment of Acute Exacerbations of COPD," <i>Clin. Drug Invest.</i> <u>22(6)</u> : 369-376 (2002)
kw	CJ	Derwent#010743444, WPI Acc No.:1996-240399/199625 for German Patent Application DE 19541689, "Medicament contg. ciclesonid and beta2-sympathomimetic - for treating chronic obstructive respiratory disease,"

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W. W. W. W. W.

DATE CONSIDERED

1-17-03

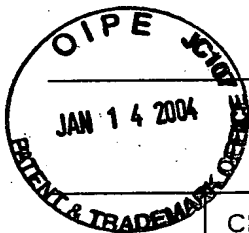
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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

CK	Derwent#012030009, WPI Acc No.:1998-446919-199838 for PCT Patent Application WO 98/34595, "Pressurised liquid aerosol propellant for pharmaceutical inhalers-contains carbon dioxide and hydro-fluoroalkane; gives more consistent dosing and a better particle size spectrum,"
CL	Derwent#013011051, WPI Acc No.:2000-182903/200016 for PCT Patent Application WO 00/06121, "Aerosol propellant comprising dinitrogen monoxide and hydrofluoroalkane and optionally containing a pharmaceutically active substance,"
CM	Derwent#013023586, WPI Acc No. 2000-195437/200017, for PCT Patent Application WO 00/07567 "Aerosol formulation for drug administration, containing small amount of cromoglycate or nedocromil salt as drug carrier, to improve dispersion stability and accuracy of dosing,"
CN	Derwent#013024375, WPI Acc No.: 2000-196226/200018 for German Patent Application DE 19835346, "Two-part drug capsule for use in powder inhalers is formed from hydrophobic plastics, preferably high density polyethylene,"
CO	Derwent#013227765, WPI Acc No. 2000-399639/200034, for PCT Patent Application, WO 00/28979 "Use of magnesium stearate for stabilization of dry powder inhalation formulations to improve resistance to moisture,"
CP	Derwent#013790372, WPI Acc No.: 2001-274583/200129, for PCT Patent Application, WO 01/22956 "Drug combination of soft steroid and beta-2-adrenoceptor agonist, administered by inhalation for effective treatment of respiratory or allergic diseases, e.g. asthma,"
CQ	Derwent#014808338, WPI Acc No.:2002-629044/200268, for PCT Patent Application, WO 02/060533 "Medicament containing a betamimetic and an oxitropium salt useful for the treatment of respiratory disorders with reduced side effects,"
CR	Derwent#014816787, WPI. Acc No.: 2002-637493/200269, for PCT Patent Application, WO 02/060532 "Medicament containing a betamimetic and an ipratropium salt useful for the treatment of respiratory disorders with reduced side effects,"
CS	Eickelberg <i>et al.</i> , "Ligand-independent Activation of the Glucocorticoid Receptor by $\delta_2$ -Adrenergic Receptor Agonists in Primary Human Lung Fibroblasts and vascular Smooth Muscle Cells," <i>The Journal of Biological Chemistry</i> <u>274(2)</u> : 1005-1010 (1999)
CT	Farmer <i>et al.</i> , " $\delta$ -Adrenergic agonists exert their "anti-inflammatory" effects in monocytic cells through the I $\kappa$ B/NF- $\kappa$ B pathway," <i>Am. J. Physiol. Lung. Cell. Mol. Physiol.</i> <u>279</u> : 1675-682 (2000)
CU	Greening <i>et al.</i> , "Added salmeterol versus higher-dose corticosteroid in asthma patients with symptoms on existing inhaled corticosteroid," <i>The Lancet</i> <u>344</u> : 219-224 (1994)

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22 JAN 2004

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

CV	Grootendorst <i>et al.</i> , "Effect of oral prednisolone on the bronchoprotective effect of formoterol in patients with persistent asthma," <i>Eur. Respir. J.</i> <u>17</u> : 374-379 (2001)
CW	Ida, Hisashi, "Pharmacology of Formoterol, ( $\alpha$ RS)-3-formamido-4-hydroxy- $\alpha$ -[[[( $\alpha$ RS)- <i>p</i> -methoxy- $\alpha$ -methylphenethyl] amino] methyl] benzylalcohol fumarate dihydrate (BD 40A)," <i>Oyo Yakuri</i> <u>21(2)</u> : 201-210 (1981)
CX	Ito <i>et al.</i> , "Glucocorticoid Receptor Recruitment of Histone Deacetylase 2 Inhibits Interleukin-16-Induced Histone H4 Acetylation on Lysines 8 and 12," <i>Molecular and Cellular Biology</i> <u>20(18)</u> : 6892-6903 (2000)
CY	Ito <i>et al.</i> , "p65-activated Histone Acetyltransferase Activity Is Repressed by Glucocorticoids," <i>The Journal of Biological Chemistry</i> <u>276(32)</u> : 30208-30215 (2001)
CZ	Korn <i>et al.</i> , "Effects of formoterol and budesonide on GM-CSF and IL-8 secretion by triggered human bronchial epithelial cells," <i>Eur. Respir. J.</i> <u>17</u> : 1070-1077 (2001)
DA	Lipworth <i>et al.</i> , "Effects of Treatment with Formoterol on Bronchoprotection against Methacholine," <i>Am. J. Med.</i> <u>104</u> : 431-438 (1998)
DB	Malolepszy <i>et al.</i> , "Safety of formoterol Turbuhaler™ at cumulative dose of 90 $\mu$ g in patients with acute bronchial obstruction," <i>Eur. Respir. J.</i> <u>18</u> : 928-934 (2001)
DC	O'Connor, B.J., "Combination Therapy," <i>Pulmonary Pharmacology &amp; Therapeutics</i> <u>11</u> : 397-399 (1998)
DD	Oddera <i>et al.</i> , "Salmeterol Enhances the Inhibitory Activity of Dexamethasone on Allergen-Induced Blood Mononuclear Cell Activation," <i>Respiration</i> <u>65</u> : 199-204 (1998)
DE	Package Insert for: ADVAIR™ DISKUS <a href="http://fb.a-files.net/PackageInsert/Advair.htm">http://fb.a-files.net/PackageInsert/Advair.htm</a> (accessed on 09/26/02) (Copyright, 1999 Glaxo Wellcome Inc.)
DF	Palmqvist <i>et al.</i> , "Onset of Bronchodilation of Budesonide/Formoterol vs. Salmeterol/Fluticasone in Single Inhalers," <i>Pulmonary Pharmacology &amp; Therapeutics</i> <u>14</u> : 29-34 (2001)
DG	Pang, L. and A.J. Knox, "Regulation of TNF- $\alpha$ -induced eotaxin release from cultured human airway smooth muscle cells by $\delta_2$ -agonists and corticosteroids," <i>FASEB J.</i> <u>15</u> : 261-269 (2001)
DH	Pang, L. and A.J. Knox, "Synergistic Inhibition by $\delta_2$ -Agonists and Corticosteroids on Tumor Necrosis Factor- $\alpha$ -Induced Interleukin-8 Release from Cultured Human Airway Smooth-Muscle Cells," <i>Am. J. Respir. Cell Mol. Biol.</i> <u>23</u> : 79-85 (2000)
DI	Pauwels <i>et al.</i> , "Effect of Inhaled Formoterol and Budesonide on Exacerbations of Asthma," <i>The New England Journal of Medicine</i> <u>337(20)</u> : 1405-1411 (1997)

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

W	DJ	Schreurs <i>et al.</i> , "A dose-response study with formoterol Turbuhaler™ as maintenance therapy in asthmatic patients," <i>Eur. Respir. J.</i> <u>9</u> : 1679-1683 (1996)
	DK	Seldon <i>et al.</i> , "Albuterol Does Not Antagonize the Inhibitory Effect of Dexamethasone on Monocyte Cytokine Release," <i>Am. J. Respir. Crit. Care Med.</i> <u>157</u> : 803-809 (1998)
	DL	Silvestri <i>et al.</i> , "Fluticasone and salmeterol downregulate <i>in vitro</i> , fibroblast proliferation and ICAM-1 or H-CAM expression," <i>Eur. Respir. J.</i> <u>18</u> : 139-145 (2001)
	DM	Sköld <i>et al.</i> , "Glucocorticoids Augment Fibroblast-Mediated Contraction of Collagen Gels by Inhibition of Endogenous PGE Production," <i>Proceedings of the Association of American Physicians</i> <u>111</u> (3): 249-258 (1999)
	DN	Stewart <i>et al.</i> , "Acute formoterol administration has no argogenic effect in nonasthmatic athletes," <i>Medicine &amp; Science In Sports &amp; Exercise</i> <u>34</u> (2): 213-217 (2002)
	DO	Vianna, E.O. and R.J. Martin, "Bronchodilators and Corticosteroids in the Treatment of Asthma," <i>Drugs of Today</i> <u>34</u> (3): 203-223 (1998)
	DP	Wilding <i>et al.</i> , "Effect of long term treatment with salmeterol on asthma control: a double blind, randomised crossover study," <i>British Medical Journal</i> <u>314</u> : 1441-1446 (1997)
W	DQ	Woolcock <i>et al.</i> , "Comparison of Addition of Salmeterol to Inhaled Steroids with Doubling of the Dose of Inhaled Steroids," <i>Am.J. Respir. Crit. Care Med.</i> <u>153</u> : 1481-1488 (1996)

EXAMINER

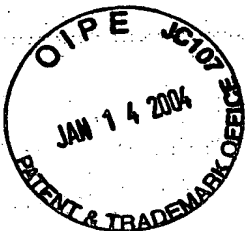
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DISCLOSURE STATEMENT (2 pages); PTO-FORM 1449 (7 pages);  
CITED REFERENCES; CHECK IN THE AMOUNT OF \$180.00; and  
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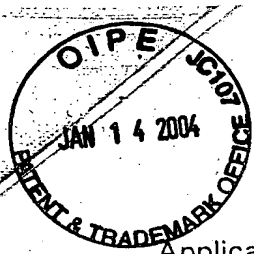
APPLICANT: Banerjee *et al.*

SERIAL NO.: 09/887,281 FILED: June 22, 2001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Banerjee *et al.*

Serial No.: 09/887,281

Conf. No.: 6268

Filed: June 22, 2001

For: *BRONCHODILATING COMPOSITIONS AND METHODS*

Art Unit: 1614

Examiner: Weddington, K. E.

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Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

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The Commissioner is hereby authorized to charge any fee, including any submitted herewith if the attached check(s) is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

By:

Dale L. Rieger  
Registration No. 43,045

November 21, 2002  
Atty Docket No. 18025-1013  
**Address all correspondence to:**  
Stephanie Seidman, Esq.  
HELLER EHRMAN WHITE & McAULIFFE LLP  
4350 La Jolla Village Drive, 7th Floor  
San Diego, California 92122  
Telephone: (858) 450-8400  
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